59. The method of claim 58 wherein said device further includes a first tubular graft connected to said resilient element, said method further comprising the steps of inserting a second device having a second substantially annular resilient element telescopically within the interior of said tubular graft and causing said second resilient element to extend outwardly to engage the interior surface of said graft.

60. The method of claim 59 wherein said second device includes a second tubular graft connected to said second resilient element.

61. The method of claim 60 further including the step of adjusting the length of said prosthetic device by adjusting the point at which the resilient element of the second device engages the interior surface of said first tubular graft.

62. The method of claim 61 further including the step of telescopically inserting a pair of stents inside the second prosthetic device to form a passage from the iliac arteries to the abdominal aortic artery.

REMARKS

Applicant hereby confirms the provisional election, with traverse, to prosecute the claims of Group I (claims 1-36 and 47-49), which was made by Timothy Trop during a telephone conversation with the Examiner on January 13, 1998.

The Examiner has rejected claims 1, 3, 6, 7, 9-11, 22, 28-29, 32-33 and 35 under 35 U.S.C. § 112, second paragraph, as being indefinite for various reasons. In addressing the Examiner's rejections, Applicant has amended claim 1 to recite that the claimed device is for retaining a prosthesis "*within* a body passage *having a diameter.*" The claim further recites that the resilient element of the device has "an undeformed diameter greater than the diameter of said body passage."

Accordingly, it is clear that the device is positioned within the body passage, yet has an undeformed diameter that is greater than the diameter of the body passage. Thus, Applicant believes that the recitation of the body passage and its diameter is definite, and operates to modify the scope of the claim.

Claims 3, 6, 7, 11, 19, 28, 30 and 33-35 have been amended to insert the word "further" before "including" in accordance with the Examiner's suggestion.

Claim 9 has been amended to clearly indicate that "said tubular graft is a fabric graft."

In claim 10, the reference to "a body passage" referred to by the Examiner has been deleted from the claim.

Claim 23 (referred to by the Examiner as claim 22) has been amended to recite an annular ring that is "movable to an undeformed state wherein said annular ring has an undeformed diameter," so that the term "undeformed diameter" no longer lacks antecedent basis.

Claim 29 has been amended to include the features of the prosthesis within the preamble, thereby overcoming the Examiner's rejection. Further, amended claim 29 now recites a device "releasably coupled to said apparatus and adapted to hold said prosthesis . . . " to positively recite the interrelationship between the apparatus and the prosthesis.

Claim 32 has been amended to clearly recite that the first and second prosthesis sections are axially aligned, and the annular spring element of the second prosthesis section communicates and engages with the internal surface of the tubular graft of the first prosthesis section. Applicant believes that claim 32 clearly recites a positive relationship between the first and second prosthesis sections.

Claims 33 and 35 have been amended to clearly recite which spring elements are being referred to therein.

In view of the above amendments, Applicant believes each of the Examiner's rejections under 35 U.S.C. § 112 have been overcome.

The Examiner has indicated that the foreign language documents contained in the Information Disclosure Statement filed on September 15, 1997

have not been considered. Each of these documents, along with a concise explanation of the same, have been resubmitted in an Information Disclosure Statement filed on April 23, 1998.

The Examiner has rejected claims 47-49 under 35 U.S.C. § 102(e) as being anticipated by Quijano et al. (U.S. Patent No. 5,500,014) without any further explanation as to the basis for the rejection. Applicant respectfully disagrees with the Examiner's rejection.

The device disclosed by Quijano et al. is a biological vein portion that, as harvested, includes within it a biological valve. The leaflets of the biological valve are chemically fixed so that they are open under normal forward blood flow, but closed under minimal backflow pressure. Applicant fails to understand the basis for the Examiner's rejection, since the device of Quijano et al. is so fundamentally and structurally different from the device of claim 47 as to lack virtually all elements of the claim. For example, nowhere in Quijano et al. is a prosthesis having a "deformable, resilient annular ring" disclosed, as is recited in claim 47, let alone a flexible tubular sleeve connected to such a ring at one end and to a prosthetic heart valve at the other end. Accordingly, since Quijano et al. fail to disclose each element of present independent claim 47, and claims 48-49 that are dependent thereon, are not anticipated by this reference.

Although Applicant believes the above explanation to be sufficient by itself, Applicant is unable to provide any further response without an explanation by the Examiner as to how the elements of the rejected claims are disclosed by the cited reference.

The Examiner has rejected claims 1-3, 6, 10, 12-13, 16-17, 19-26 and 28-31 under 35 U.S.C. § 102(b) as being anticipated by Inoue (U.S. Patent No. 5,290,305), also without further explanation.

The '305 patent discloses a collapsible stent that is used to restore a collapsed blood vessel to its original tubular shape, and that can be inserted into the body by a catheter. The device consists of a pair of annular rings (10) positioned on opposite sides of the stent, with several additional intermediate rings (12), and connecting wire rings (11) that connect the annular rings and intermediate annular

rings together. When uncompressed, the cross-section of the rings (10, 11, 12) is circular or elliptical, and the device is designed to be restored to this tubular, or fully uncollapsed state when positioned in a body passage, as is shown in the figures and as is described in the specification at Col. 2, lines 46-50. The size of the rings 10, 12, as expanded, is specified to be that of the artificial blood vessel. (Col. 5, lines 58-62). The device of the '305 patent may be released from a catheter and restored to its original tubular shape. Once released, however, it cannot be recompressed for repositioning, but rather must be moved forwardly or rearwardly while in its expanded state. Col. 9, lines 12-15.

In contrast, the device claimed in independent claims 1 and 12 includes a resilient substantially annular ring that is designed to exist in a "deformed state wherein said element is partially folded" when properly positioned within a body passage. As discussed in the specification at page 11, lines 1-25 and page 18, line 18 - page 19, line 8, this former feature is advantageous in that it provides an improved seal against the inner wall of the body passage, it improves the ability of the device to adapt to non-circular or irregularly shaped body passages, it enables the device to be adaptable to different size body passages so as to reduce inventory, and it is capable of providing a secure fit in small neck regions without occluding adjoining arteries (see Figures 4 and 5). The '305 patent does not disclose or suggest a device having the features and advantages of the presently claimed device, and in fact, teaches against it by encouraging a device that is fully expanded to its uncompressed tubular shape when positioned within a body passage. Such a device cannot provide a means for superior attachment to the surrounding body passage, and cannot avoid occlusion of intersecting vessels, as does the device of the present invention.

Amended independent claim 29 recites "a device releasably coupled to said apparatus and . . . adapted to enable said ring to be remotely expanded and recompressed when said ring is within said body passage." This claimed feature of claim 29 is advantageous in that it allows the prosthesis to be repositioned once released without dragging it in its expanded state, which avoids injury to the inner lining of the body passage. The device disclosed in the '305 patent cannot be

remotely expanded and recompressed when within a body passage, and therefore, cannot anticipate independent claim 29, or claims 30-31, which are dependent thereon.

Independent claim 21 recites a substantially annular resilient element that "when positioned within said first vessel" has a pair of loops extending in one direction and a second pair of loops extending in the opposite direction," with "one of said second pair of loops defining an opening to permit communication between said first and second vessels." As discussed above, since the device disclosed in the '305 patent is fully expanded to its tubular shape when positioned within a vessel, it does not define "an opening to permit communication between said first and second vessels," as is required by claim 21.

Accordingly, for the reasons stated above, the Inoue '305 reference does not anticipate independent claims 1, 12, 21, or 29. Likewise, by virtue of their dependence on patentable claims 1, 12, 21, and 29 respectively, dependent claims 2-11, 13-20, 22-28, and 30-31 are not anticipated by the Inoue '305 reference.

The Examiner has also rejected claims 1-4, 6, 12, 16 and 17 under 35 U.S.C. § 102(b) over Polansky, similarly without further explanation. Polansky describes a *weave pattern* for a prosthesis that integrates collagen and a non-absorbable material. The "reinforcing ring sections" of Polansky that are spaced along the tube are different from the remainder of the tube only in that they include an additional yarns that are integrated into the weave. See Col. 3, lines 15-24. Polansky does not disclose a "substantially annular resilient element," let alone such an element that is movable between a deformed state and an undeformed state, as is required by independent claims 1 and 12. In fact, the weave pattern disclosed by Polansky reference is entirely irrelevant to the present application. Accordingly, independent claims 1 and 12, and dependent claims 2-4, 6, 16 and 17, are not anticipated by Polansky.

Claims 1-6, 10, 12-13, 16-17, 19-26 and 28-31 currently stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,693,089 to Inoue. Applicant respectfully disagrees with the Examiner's rejection.

The Inoue '089 patent discloses a collapsible stent that is virtually

identical to that disclosed by the Inoue '305 patent, and a method for collapsing the same. Since the apparatus is the same as that described in the '305 patent, the present claims, as amended, are patentable over this reference for the reasons cited above in relation to the '305 patent.

As discussed above, the device disclosed in the '305 and '089 patents expand to their original entirely uncompressed tubular shape when positioned within a body cavity. This is further apparent from Col. 15, lines 7-13 of the '089 patent, which describes the necessity of an additional securing mechanism to prevent the device from being displaced from its proper position. "Thorns ... stick to the inner wall of a human organ to be imbedded therein ... [to] prevent displacement of the artificial blood vessel." This is necessary since the uncompressed device does not exert a sufficient amount of force on the inner walls of the body passage to help hold it in place.

The Examiner has further rejected claims 1, 7-9, 11-15, and 18-20 under 35 U.S.C. § 102(e) as being anticipated by Taheri (U.S. Patent No. 5,693,878) with specific reference only to Figures 10-12 and to the mention of DACRON in the reference. Applicant also respectfully disagrees with this rejection.

Taheri discloses the use of a combination graft and stent to address the problem of repairing diseased or damaged vessels of a major artery, such as the aorta, without obstructing intersecting arteries, such as renal or carotid arteries. A graft is first inserted into the aorta, then a hole is cut in the graft at the point where the renal artery (or other intersecting artery) intersects the aorta. A stent is then inserted through the hole in the graft and into the renal artery.

Although the body portion 18 of the stent is described as being flexible, and expandable by use of a balloon catheter, nowhere in the '878 patent is the collar 20 described as being resilient or flexible, as are the annular rings of the present invention. The collar is not in a deformed state when positioned within the body, as is readily apparent from the figures, and from the fact that a series of tines 21 are required to secure it to the walls of the artery. Further, Taheri does not disclose an annular ring that, when positioned in its deformed state, allows communication between a primary vessel and a second intersecting vessel, but

rather discloses a graft that must have a hole cut through it to achieve this objective.

Thus, Taheri does not disclose a device "being movable between an undeformed state and a deformed state," or a device that in said deformed state "retains said prosthesis in said body passage" as in amended independent claims 1 and 12. Accordingly, each of independent claims 1 and 12, and claims 7-9, 11, 13-15, and 18-20 which are dependent thereon, are patentable over Taheri.

The Examiner has also rejected claims 18 and 27 over Taheri under 35 U.S.C. § 103(a). Claim 18 is dependent on claim 12. As indicated above, Taheri does not teach or suggest an annular resilient element that is movable between an undeformed state and a deformed state, and that is "in said deformed state when retaining said prosthesis in said body passage," as is recited in claim 12. The device of Taheri is not secured by a resilient element in its deformed state, but rather by a round collar having tines extending outwardly from it.

With regard to claim 27, which is dependent on claim 21, recites a resilient annular ring having a first pair of loops extending past an intersecting vessel and a second pair of loops "defining an opening to permit communication between said first and second vessels." The device of the present invention avoids obstructing an intersecting vessel by utilizing its deformed configuration when properly positioned in the primary body vessel. The graft disclosed in Taheri is incapable of such a configuration, and in fact, must have a hole cut into it to avoid obstructing the intersecting vessel. Col. 4, lines 48-55. Clearly, the device of Taheri fails to disclose or suggest the device presently claimed in independent claims 12 and 21, and dependent claims 18 and 27, and therefore, fails to anticipate these claims.

The Examiner has further rejected claims 7-9, 14 and 15 under 35 U.S.C. § 103 as being unpatentable over Inoue '305 or Inoue '089 in view of Porter '435. As indicated above, neither Inoue '305 or Inoue '089 disclose a device that when in a partially folded deformed state retains a prosthesis within a body cavity, as is required by claims 1 and 12 of the present application. Similarly, Porter does not disclose such a device. Porter discloses a resilient stent made of "open weave, helical and braided construction." Col. 2, lines 52-56. The device does not include

a "substantially annular resilient ring element" that is "folded" when retaining a prosthesis within a body cavity. As previously discussed, this feature is unique and advantageous in that it permits the prosthesis to be inserted into a body cavity such as the aortic artery, at the area of intersection of another artery, such as a renal artery, without obstructing the intersecting artery. Since Porter does not teach or suggest a device that exists within a body vessel in a "folded" deformed state, it is incapable of providing the advantages of the device claimed in the present application. Accordingly, since the combination of Inoue '305, Inoue '089 and Porter '435 do not teach or suggest a device having all the elements recited in amended claims 1 and 12, these claims are patentable over the cited references. Further, by virtue of their dependence on patentable claims 1 and 12 respectively, dependent claims 7-9 and 14-15 are also patentable over the cited references.

Finally, the Examiner has rejected claims 32-36 under 35 U.S.C. § 103 over Porter '435 in view of Inoue '305. Claim 32 has been amended to include the following limitation that is also present in claims 1 and 12:

> said first resilient element being movable between an undeformed state wherein said element has an undeformed diameter greater than the diameter of said body passage, and a deformed state wherein said element is partially folded and has a diameter smaller than when in said undeformed state, said element being in said deformed state when retaining said prosthesis in said body passage.

As state above, neither Porter nor Inoue '305 teach or suggest a device that exists in a deformed folded state when retaining a prosthesis within a body passage, and therefore, a device that is capable of use in the area of intersection of two vessels, as is the device of the present application. Thus, independent claim 32, and dependent claims 33-36 are patentable over the cited references.

For the reasons stated above, Applicant believes that each of pending claims 1-36 and 47-51, and new claims 52-62 are patentably distinct over each of the references, alone or in combination, that were cited by the Examiner. Accordingly, Applicant respectfully requests reconsideration and allowance of all pending claims.

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Respectfully submitted,

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